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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,960	11/21/2000	Michael Brines	10165-009-999	6595
20583	7590	01/19/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			DEBERRY, REGINA M	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/716,960	Applicant(s) BRINES ET AL.	
	Examiner Regina M. DeBerry	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,9 and 11-27 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6,8,9 and 11-14 is/are allowed.
- 6) ☒ Claim(s) 15-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Status of Application, Amendments and/or Claims

The amendment filed 03 November 2004 has been entered in full. Claims 7 and 10 were cancelled. New claims 14-27 were added. Claims 1-6, 8, 9, 11-27 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection to claims 1-6, 8-13 under 35 U.S.C. 112, first paragraph, scope of enablement, as set forth at pages 2-4 of the previous Office Action (16 September 2004) is *withdrawn* in view of the amendment (03 November 2004).

Claim Rejections - 35 USC § 112, first paragraph, scope of enablement

New claims 15-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

a method for **protecting** against injury or damage to neural tissue in a mammal, **wherein said injury or damage is caused by mechanical trauma, multiple sclerosis, diabetic neuropathy and amyotrophic lateral sclerosis**, comprising administering peripherally to a mammal in need thereof an effective non-toxic amount of EPO for the protection against injury or damage of the neural tissue,

does not reasonably provide enablement for

a method for treating or protecting against injury or damage to neural tissue in a mammal, comprising administering peripherally to a mammal in need thereof an effective non-toxic amount of EPO for treatment or protection of the neural tissue.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant states that the new claims have been amended to replace "neurodegenerative condition" (of claim 1) with "injury or damage to neural tissue", which is the underlying factor in neurodegenerative conditions encompassed by the instant invention. Applicant cites pages from the instant specification, including Example 5 and Example 7. Applicant states that the Declaration of Michael Brines, submitted February 26, 2003, also demonstrates successfully treating or protecting against injury or damage to neural tissue in mammals in accordance with the teachings of the specification.

Applicant's arguments have been fully considered, but are not deemed persuasive. Example 5 of the instant specification teaches the administration of EPO to mice 24 hours before blunt trauma, at the time of blunt trauma, 3, 6, or 9 hours later. When animals were pre-treated with EPO or given EPO up to 3 hours after injury, the volume of brain necrosis was less than the control. Example 7 teaches that experimental allergic encephalomyelitis (EAE) in rats is an art accepted animal model for multiple sclerosis. Rats were treated with EPO, assessed for signs of EAE and scored for either no disease (0), flaccid tail (1), ataxia (2), and/or complete hind limb

paralysis with urinary incontinence (3). Rats treated with EPO demonstrated an improvement in score versus the control. The Brines Declaration teaches a reduction of the severity of the neurodegenerative symptoms in diabetic neuropathy and amyotrophic lateral sclerosis animal models treated with EPO.

The scope of patent protection sought by Applicant as defined by the claims fails to bear a reasonable correlation with the scope of enabling disclosure set forth in the specification because the instant claims can encompass any injury or damage such as injury or damage to a human spinal cord caused by an automobile accident or brain injury or damage caused by a bullet wound. The instant specification fails to teach the treatment or protection against "any type of injury or damage" to "any type of neural tissue" in a mammal. Furthermore, the specification fails to demonstrate that EPO is actually "treating" the injured or damaged neural tissue in a mammal. The examples disclosed in the instant specification and declaration, demonstrated some protection of neural tissue upon peripherally administering EPO, but these results are not correlative with "treating or protecting against injury or damage to neural tissue in a mammal". Reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

Due to the large quantity of experimentation necessary to treat or protect against injury or damage to neural tissues in a mammal comprising administering peripherally EPO, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention and the breadth of the claims which fail to recite limitations regarding the type of injury,

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damage or neural tissue, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Conclusion

Claims 1-9,11-14 are allowed.

Claims 15-27 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

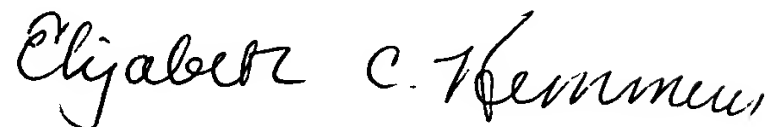
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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EXAMINER'S
PRIMARY SIGNATURE